Registration Decision RD2013-15

Spinetoram

(publié aussi en français)

23 July 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2013-15E (print version)
H113-25/2013-15E-PDF (PDF version)

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Registration Decision for Spinetoram

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Spinetoram Technical Insecticide, Radiant SC Insecticide and Delegate WG Insecticide, containing the technical grade active ingredient spinetoram, to control or suppress a variety of foliage-feeding insect pests in orchard, vineyard, and field crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-31, *Spinetoram*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for spinetoram and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2012-31. This decision is consistent with the proposed registration decision stated in PRD2012-31.

For more details on the information presented in this Registration Decision, please refer to PRD2012-31, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Spinetoram?

Spinetoram is a non-systemic insecticide derived from the fermentation of *Saccharopolyspora spinosa*. The end-use products Radiant SC Insecticide and Delegate WG Insecticide are applied using ground-based foliar application equipment to control a variety of insect pests on a wide range of fruit, vegetable and cereal crops. Spinetoram affects insects through both contact and ingestion, but is most active through ingestion.

Health Considerations

Can Approved Uses of Spinetoram Affect Human Health?

End-use products containing spinetoram are unlikely to affect your health when used according to label directions.

Exposure to spinetoram may occur through diet (food and water) or when handling and applying the end-use products. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using pesticide products according to label directions.

In laboratory animals, the technical grade active ingredient spinetoram was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was non-irritating to the eyes and skin, but considered to be a potential skin sensitizer. Consequently, the statement "Potential Dermal Sensitizer" is required on the label. Based on the acute toxicity data, no hazard labelling was necessary for the end-use products Radiant SC Insecticide or Delegate WG Insecticide.

Spinetoram did not cause cancer in laboratory animals and was non-genotoxic. There was no indication that spinetoram caused damage to the nervous system. Health effects in animals given repeated doses of spinetoram included effects on the thyroid gland, lymphoid tissues, kidneys, spleen and blood system. Spinetoram did not cause birth defects in laboratory animals. When spinetoram was given to pregnant animals, fetal death was observed at doses which were also toxic to the mother, as demonstrated by difficulty in delivering their young. The potential for increased sensitivity of the lungs following repeated inhalation exposure necessitated the application of extra protective factors in the inhalation risk assessment to further reduce the

allowable level of human exposure to spinetoram.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate refined dietary intake estimates (food plus water) revealed that the general population and children, the subpopulation which would ingest the most spinetoram relative to body weight, are expected to be exposed to less than 11.3% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from exposure to spinetoram residues is not of concern for any of the population sub-groups.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established under the authority of the *Food and Drugs Act* through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Processing studies conducted on oranges and grapes in the United States and France, using the end-use product containing spinetoram, were acceptable. The MRLs for this active ingredient are accessible on the PMRA's MRL webpage. The MRLs for grape juice, raisins, and citrus oil will be revised to reflect the results of the submitted processing studies.

Occupational Risks From Handling Radiant SC Insecticide and Delegate WG Insecticide

Occupational risks are not of concern when Radiant SC Insecticide and Delegate WG Insecticide are used according to the proposed label directions, which include protective measures.

The label will specify that anyone mixing or loading Radiant SC Insecticide or Delegate WG Insecticide, or performing clean-up or repair activities, must wear coveralls over long-sleeved shirt and long pants, shoes plus socks and chemical-resistant gloves. Workers applying either product must wear long-sleeved shirt and long pants, shoes and socks and chemical-resistant gloves. Taking into consideration these label requirements, risk to workers handling Radiant SC Insecticide or Delegate WG Insecticide is not of concern.

Environmental Considerations

What Happens When Spinetoram Is Introduced Into the Environment?

Spinetoram rapidly transforms in the terrestrial and aquatic environment. The parent compound and its major transformation product, N-demethyl-J, are non-persistent in the environment and have a low potential for residue carryover. They also have a low potential to leach and contaminate groundwater. Based on its low volatility, spinetoram residues are not expected in the air.

Spinetoram may pose a risk to bees, predatory and parasitic arthropods, non-target terrestrial plants, wild mammals, freshwater invertebrates (daphnids and benthic organisms); therefore, statements on the product labels are required to inform users of the potential risks. In order to minimize the potential for exposure resulting from off-field spray drift, no-spray buffer zones are required between the treated area and downwind terrestrial habitats.

Value Considerations

What Is the Value of Radiant SC Insecticide and Delegate WG Insecticide?

Radiant SC Insecticide and Delegate WG Insecticide control or suppress a variety of insect pests of fruit, vegetable and cereal crops.

Application of Radiant SC Insecticide or Delegate WG Insecticide provides control or suppression of a variety of insect pests of fruit, vegetable and cereal crops and is compatible with current management practices and conventional crop production systems. Growers are familiar with the monitoring techniques to determine if and when applications are needed.

One other active ingredient in the same class as spinetoram is registered for some of the same uses; however, spinetoram is registered for use against a broader range of pests. Spinetoram provides a new alternative active ingredient for uses that have traditionally relied on older classes of chemistry as well as uses that have few other registered alternatives.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Radiant SC Insecticide and Delegate WG Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Environment

Spinetoram can pose a risk to bees, predatory and parasitic arthropods, wild mammals and freshwater invertebrates (daphnids and benthic organisms). Label statements informing the users of the potential risks to these organisms are specified on the product labels.

Spray drift of spinetoram can pose a risk to non-target terrestrial plants. To minimize potential exposures via spray drift, no-spray buffer zones of one to two metres are required to protect sensitive terrestrial habitats. These no-spray buffer zones are specified on the product labels.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-31, *Spinetoram)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act.*